SEP 2 2 2008

K080803

510(k) Summary

510(k) Submitter/ Owner	Herbert Cameron III President American Optisurgical, Inc. Email: cameron@optisurgical.com
Contact person	David Salzberg Director of Regulatory Affairs American Optisurgical, Inc. Email: regulatory@optisurgical.com
Date prepared	03/20/2008
Trade name	Vizual™ Phacoemulsification System, Model 551
Common name	Phacoemulsification System
Classification	Phacofragmentation system (21 CFR 886.4670, Product Code HQC)
Predicate device	K020527, Horizon Phacoemulsification System (manufactured by American Optisurgical, Inc.)
Device description	The Vizual™ Phacoemulsification system is a complete anterior segment surgical system, offering Irrigation, Phaco or Ultrasonic (U/S), Irrigation/Aspiration (I/A), Vitrectomy, and Coagulation modes of operation. The device can be operated as a standalone unit, or connected to an optional cart with electric I/V pole where bottle height can be controlled by the software. The Vizual™ Phacoemulsification System includes the Phaco unit, U/S handpiece, tubing cartridge, and foot pedal. The device has been designed to work with commercially available (and 510k cleared) components and accessories including Phaco tips and sleeves, vit cutters, cautery pencils, and cautery forceps. The Vizual™ Phacoemulsification System utilizes a non-invasive vacuum sensing system including an external tubing cartridge that vents to the bottle versus air, thus

minimizing the possibility of introducing contamination into the fluid path. The external tubing cartridge design is advantageous as the fluid path is visible to the user, and can be easily installed or removed in a single step.

The Vizual™ Phacoemulsification System uses a LCD touch panel interface to allow access to all modes of operation. The system software allows for storing up to twenty-four different user profiles.

Intended use

The Vizual™ Phacoemulsification System is intended for use in the disruption and extraction of cataractous lens material from the eye with ultrasonic energy, a process known as phacoemulsification.

Technological characteristics

The Vizual™ Phacoemulsification System has the same technological characteristics as the predicate device cleared under 510(k) K020527. A summary is as follows:

Table II – Summary of Device Characteristics

Device Characteristics	Subject Device	Predicate Device
Display	LCD Touch Screen	LCD Touch Screen
Pump	Peristaltic, low pulsation	Peristaltic, low pulsation
Pump Vacuum Range	0 to 500 mmHg	0 to 500 mmHg
Aspiration Rate	0 to 50 cc/min	0 to 50 cc/min
Fluidics	External Fluid Path	External Fluid Path
System Tubing	Tubing/Cartridge unit (reusable and disposable models)	Tubing/Cartridge unit (reusable and disposable models)
Vent	Fluid Vent	Fluid Vent
Modes	Irrigation, Phaco, Irrigation/Aspiration (I/A), Vitrectomy, and Coagulation	Irrigation, Phaco, Irrigation/Aspiration (I/A), Vitrectomy, and Coagulation
Programmable User Parameters	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2008

American Optisurgical, Inc.
c/o David Salzberg
25501 Arctic Ocean
Lake Forest, CA 92630

Re: K080803
Trade/Device Name: Vizual™ Phacoemulsification System, Model 551
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacoemulsification System
Regulatory Class: II
Product Code: HQC
Dated: August 20, 2008
Received: August 20, 2008

Dear Mr. Salzberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K080803

Device Name: Vizual™ Phacoemulsification System

Indications for Use: The Vizual™ Phacoemulsification System is intended for use in the disruption and extraction of cataractous lens material from the eye with ultrasonic energy; a process known as phacoemulsification.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K080803